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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/426,038	10/25/1999	JESPER VIND	5579.210-US	1334

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EXAMINER
PONNALURI, PADMASHRI

ART UNIT	PAPER NUMBER
1627	

DATE MAILED: 08/26/2002 14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/426,038	Vind
Examiner	**Art Unit**
Padmashri Ponnaluri	1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 4, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-11, 13-22, and 27-32* is/are pending in the application.

4a) Of the above, claim(s) *10, 19, 22, and 27-29* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-9, 11, 13-18, 20, 21, and 30-32* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The amendment C, filed on 6/4/02 has been fully considered and entered into the application.

2. Claim 12 has been canceled and new claims 31-32 have been added by the amendment C, filed on 6/4/02.

3. Claims 1-11, 13-22, 27-32 are currently pending in this application.

4. Claims 22, 27-29 are withdrawn from further consideration by the examiner, 37 CAR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 7.

5. Claims 10, 19 are withdrawn from further consideration by the examiner, 37 CAR 1.142(b) as being drawn to a non-elected species. Election was made **without** traverse in Paper No. 7.

6. Claims 1-9, 11, 13-18, 20-21, 30-32 are currently being examined in this application.

7. The scope enablement rejection of record has been withdrawn in view of applicants amendments and arguments filed on 6/4/02.

8. The rejections of claims under 35 U. S. C. . 112, second paragraph have been withdrawn in view of amendments to the claims. NOTE that the rejection of claims under 'incomplete or omitted essential subject matter has been maintained.

9. The indicated allowability of claims 12-14, 17 is withdrawn in view of the newly discovered reference(s) to Alexei Aleksenko et al (Molecular Microbiology (1996) 19 (3), 565-574). Rejections based on the newly cited reference(s) follow.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-9, 11, 13-~~21~~ 18, 20-21, 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christensen (WO 98/01470), Aleksenko et al (Molecular Microbiology (1996) 19 (3), 565-574) and Dalboge et al (Mol. Gen. Genet (1994) 243: 253-260.).

Christensen teaches that a transcription factor regulating alpha amylase promoter initiated expression in filamentous fungi, especially in Aspergilli, (refers to instant claim 20) DNA sequences encoding for said factor, its transformation into and expression in fungal host

organisms, and the use of said factor (i.e., see the abstract). The reference teaches a method of producing a filamentous fungal cell comprising the introduction of a DNA fragment coding for any such factor in to a filamentous fungus, wherein alpha amylase promoter or a co-regulator promoter regulates the expression of a polypeptide of interest in a manner whereby said promoter will be expressed in said fungus (i.e., see pages 3-4) (refers to instant claim 1). The reference teaches that DNA sequence encoding transcription factor homologous to the transcription factor of the invention, the DNA sequences may be derived by similar screening of cDNA library of another microorganism. The reference teaches that the method of producing a filamentous fungal host cell comprising the introduction of any of the DNA fragments into a filamentous fungus wherein the alpha amylase promoter or another coregulated promoter regulates the expression of a polypeptide of interest in a manner whereby said factor will be expresses in said fungus (i.e., see page 12, lines 29-34). The reference teaches that the invention provides a recombinant expression vector comprising DNA construct of the invention (i.e., see page 13, lines 4-5). The reference teaches that the expression vector of the invention is autonomous replicating vector (i.e., see page 13). The reference teaches suitable promoters for use in filamentous fungal cells (i.e., see pages 13-14) (refers to instant claim 8). The reference teaches a method of producing a polypeptide of interest, whereby a host cell is grown under conditions conductive to the production of said factor and said polypeptide of interest, and the polypeptide of interest is recovered (i.e., see page 15) (refers to instant claim 1, steps b and c). The reference teaches that the method may also be used for production of industrial enzymes such as hydrolases, proteases,

lipase, amylases.... (i.e., see pages 15 and 16) (refers to instant claim 4-5), and proteases (see page 16, line 1) (refers to instant claim 6). The reference teaches that the transcription factor is used to identify the sequences which bind to alpha amylase promoter to which it binds, by using GST fusion protein .

Aleksenko et al teach plasmid vector AMA1(autonomously replicating sequence) in Aspergillus nidulans, and isolated the AMA1 sequence (refers to the sequences of the instant claims) from a genomic library of A.nidulans. The reference teaches that the structural features of AMA1 and its ability to promote extrachromosomal plasmid replication. The reference teaches that the AMA1 has enhanced co-transformation efficiency. The reference teaches that AMA1 gave highest frequency transformants, and only in these transformants were recombinant plasmid detected in mycelium at high copy number.

The claimed invention differs from the prior art teachings by reciting that the vector comprises a fungal selection marker.

Aleksenko et al teach plasmid vector AMA1. Aleksenko teaches that the AMA1 has enhanced co-transformation efficiency. Christensen teaches a method of producing a filamentous fungal cell comprising the introduction of a DNA fragment coding for any such factor in to a filamentous fungus, wherein alpha amylase promoter or a co-regulator promoter regulates the expression of a polypeptide of interest in a manner whereby said promoter will be expressed in said fungus. Christensen teaches the use of GST fusion protein.

Aleksenko et al and Christensen do not use a fungal selection marker. However, it is known to use different markers in the vectors, such that the cells would be grown in a selective medium, in which particular cells of interest would be able to grow well or distinguish themselves from the others. Dalboge et al teach a novel method for efficient expression cloning of fungal enzyme genes. The reference teaches a cloning system which is independent of specific yeast strains and thus can be applied to non-essential enzymes. The flow diagram in Fig.1 teaches the disclosed method. The reference teaches a method for expression of cloned genes in Aspergillus. The reference teaches that vector pHD414 was introduced into a A.oryzae by cotransformation with amdS gene containing plasmid (which refers to the selection marker of the instant claims). The reference teaches that the transformants are isolated and assayed for enzyme activity.

Thus, it would have been obvious to one skilled in the art at the time the invention was made to use a fungal selection marker in the vectors of Christensen, such that the fungal cells having the gene of interest is identified under specific growth conditions in which the selection marker is expressed. It would have been obvious to use the sequences of AMA1 replicator in the vectors of Christensen, because Aleksenko teaches that the AMA1 has enhanced co-transformation efficiency. A person skilled in the art would have been motivated to use a fungal selection marker in the vectors taught by Christensen so that the cells carrying the gene of interest would be identified.

12. No claims are allowed.

13. Applicant's arguments filed on 6/4/02, regarding 'incomplete or omitting essential steps' have been fully considered but they are not persuasive.

Applicants argue that claim 1 recites a screening method and includes the steps of transforming fungal cells with library of polynucleotides, and cultivating the cells, , and selecting or screening for one or more transformants expressing a desired characteristics.

Applicants arguments have been considered but are not persuasive, because the claims do not recite how the transformants are selected. The rejections of record have been maintained for the reasons of record.

14. Applicant's arguments with respect to the art rejections of claims have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday to Friday from 7.00 AM to 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Mckane, can be reached on (703) 308-4537. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

P. Ponnaluri
Patent Examiner
Technology Center 1600
Art Unit 1627
22 August 2002

PADMASHRI PONNALURI
PRIMARY EXAMINER